



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Thomas M. Jessell et al.

Serial No.: 09/654,462 Group Art Unit: 1632

Filed : September 1, 2000 Examiner: A.M. Falk, Ph.D.

For : GENETIC DEMONSTRATION OF REQUIREMENT FOR NKX6.1

AND NKX2.2 IN VENTRAL NEURON GENERATION

Date of Notice

of Allowance: January 5, 2005 Confirmation No.: 6093

Issue Fee Due: April 5, 2005

1185 Avenue of the Americas New York, New York 10036 January 24, 2005

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

A Notice of Allowance was issued by the United States Patent and Trademark Office on January 5, 2005 in connection with the above-identified application. Therefore, the issue fee is due on April 5, 2005. Accordingly, this supplemental Information Disclosure Statement and accompanying Request for Continued Examination ("RCE") in compliance with 37 C.F.R. §1.114, which are being submitted in lieu of paying the issue fee, are considered timely.

Applicants are filing this supplemental Information Disclosure Statement to supplement the Information Disclosure Statement filed on October 23, 2001, and the supplemental Information Disclosure Statements filed on February 13, 2002, July 16,

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2004 and November 9, 2004 in connection with the subject application.

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §1.97(b)(4), applicants direct the Examiner's attention to the references which are listed on the attached Form PTO-1449 (Exhibit A). Copies of references 4 and 7-8 are attached hereto as Exhibits 1-3, respectively.

- 1. PCT International Application No. PCT/US95/02315, filed February 24, 1995, International Publication No. WO95/23223 A1, published August 31, 1995 on behalf of The Trustees of Columbia University in the City of New York;
- 2. PCT International Application No. PCT/GB98/01862, filed June 25, 1998, International Publication No. WO99/00516 A2, published January 7, 1999 on behalf of Medical Research Council;
- 3. PCT International Application No. PCT/US99/22517, filed September 29, 1999, International Publication No. W000/18884 A1, published April 6, 2000 on behalf of The Trustees of Columbia University in the City of New York;
- 4. PCT International Application No. PCT/US99/18525, filed August 13, 1999, International Publication No. WO00/09676 A2, published February 24, 2000 on behalf of California Institute of Technology (Exhibit 1);
- 5. Briscoe, J. et al. (1999) "Homeobox gene Nkx2.2 and

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specification of neuronal identity by graded Sonic hedgehog signalling," Nature 398: 622-627;

- 6. Cai, J. et al. (1999) "Expression and regulation of the chicken Nkx-6.2 homeobox gene suggest its possible involvement in the ventral neural patterning and cell fate specification," Developmental Dynamics 216: 459-468;
- 7. Cai, J. et al. (2001) "Mice lacking the Nkx6.2 (Gtx) homeodomain transcription factor develop and reproduce normally," Molecular and Cellular Biology 21: 4399-4403 (Exhibit 2);
- 8. Palmer, T.D. et al. (1999) "Fibroblast growth factor-2 activates a latent neurogenic program in neural stem cells from diverse regions of the adult CNS," The Journal of Neuroscience 19: 8487-8497 (Exhibit 3);
- 9. Qiu, M. et al. (1998) "Control of anteroposterior and dorsoventral domains of Nkx-6.1 gene expression relative to other Nkx genes during vertebrate CNS development,"

  Mechanisms of Development 72: 77-88;
- 10. Sander, M. et al. (2000) "Ventral neural patterning by Nkx, homeobox genes: Nkx6.1 controls somatic motor neuron and ventral interneuron fates," Genes & Development 14: 2134-2139; and
- 11. Tanabe, Y. et al. (1998) "Specification of motor neuron identity by the MNR2 homeodomain protein," Cell 95: 67-

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80.

European Patent Application No. 01968382.0, filed August 31, 2001, is the regional stage application of PCT International Application No. PCT/US01/27256, filed August 31, 2001, which is the foreign counterpart claiming priority of and the benefit under 35 U.S.C. §120 of the subject application. A Supplementary Partial European Search Report was issued by the European Patent Office on December 12, 2004 in connection with European Patent Application No. 01968382.0. A copy of the Search Report is attached hereto as Exhibit B. Above listed references 1-11 were cited in the Search Report. Applicants attach hereto copies of references 4, 7 and 8 as Exhibits 1-3, respectively.

Applicants note that above-listed references 5 and 9 were previously submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on October 23, 2001 in connection with this application.

Applicants also note that above-listed references 6 and 11 were previously submitted to and considered by the United States Patent and Trademark Office in a supplemental Information Disclosure Statement filed on July 16, 2004 in connection with this application.

Applicants further note that above-listed references 1-3 and 10 were previously submitted to and considered by the United States Patent and Trademark Office in a supplemental

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Information Disclosure Statement filed on November 9, 2004 in connection with this application.

Accordingly, copies of above-listed references 1-3, 5-6, and 9-11 are not provided herewith since they were previously submitted to the United States Patent and Trademark Office for consideration in connection with the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$395.00 RCE filing fee, is deemed necessary in connection with the filing of this supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: . Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

m P. White g. No. 28,678

White John P(. Registration No. 28,678 Attorney for Applicants Cooper & Dunham, LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400

TO-1449

EXAMINER

SIGNATURE

## **U.S. Department of Commerce Patent and Trademark Office**

Application Number 09/654,462

# FORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date	September 1, 2000
First Named Inventor	Thomas M. Jessell
Art Unit	1632
Examiner Name	A.M. Falk, Ph.D.
Attorney Docket No.	62166/JPW/MVM

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Examiner Initials	Cite No.1	Document Number Number-Kind Code <sup>2 (if known)</sup>	Publication Date N MM-DD-YYYY		Name of Patentee or Applicant of Cited Document	
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Examiner			<u> </u>	PATENT DOO	CUMENTS	
Initials*	Cite No.1	Foreign Patent Document Country Co Number <sup>4-</sup> Kind Code <sup>5 (If known)</sup>		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
	Cite No. <sup>1</sup>			Publication Date	Name of Patentee or Applicant of Cited	T <sup>6</sup>
		Foreign Patent Document Country Co Number <sup>4</sup> Kind Code <sup>5 (if known)</sup>		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document  The Trustees of Columbia University	T <sup>6</sup>
	1	Foreign Patent Document Country Condent Number Kind Code (If known)  WO95/23223 A1		Publication Date MM-DD-YYYY 08-31-1995	Name of Patentee or Applicant of Cited Document  The Trustees of Columbia University in the City of New York	T <sup>6</sup>

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds of Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English Language Translation is attached.

DATE CONSIDERED

Applicant: Thomas M. Jessell et al. U.S. Serial No.: 09/654,462 Filed: September 1, 2000

Exhibit A



## **U.S. Department of Commerce Patent and Trademark Office**

#### 09/654,462 Application Number September 1, 2000 Filing Date First Named Inventor Thomas M. Jessell Art Unit 1632

### INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

A.M. Falk, Ph.D. Examiner Name Attorney Docket No. 62166/JPW/MVM

Attorney Docket No.  62166/JPW/MVM							
		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>						
	5	Briscoe, J. et al. (1999) "Homeobox gene <i>Nkx2.2</i> and specification of neuronal identity by graded Sonic hedgehog signalling," <i>Nature</i> 398: 622-627;					
	6	Cai, J. et al. (1999) "Expression and regulation of the chicken Nkx-6.2 homeobox gene suggest its possible involvement in the ventral neural patterning and cell fate specification," <i>Dev. Dyn.</i> 216: 459-468;					
	7	Cai, J. et al. (2001) "Mice lacking the Nkx6.2 (Gtx) homeodomain transcription factor develop and reproduce normally," Molecular and Cellular Biology 21: 4399-4403;					
	8	Palmer, T.D. et al. (1999) "Fibroblast growth factor-2 activates a latent neurogenic program in neural stem cells from diverse regions of the adult CNS," <i>The Journal of Neuroscience</i> 19: 8487-8497;					
	9	Qiu, M. et al. (1998) "Control of anteroposterior and dorsoventral domains of Nkx-6. I gene expression relative to other Nkx genes during vertebrate CNS development," Mechanisms of Development 72: 77-88;					
	10	Sander, M. et al. (2000) "Ventral neural patterning by Nkx homeobox genes: Nkx6.1 controls somatic motor neuron and ventral interneuron fates," Genes & Development 14: 2134-2139; and					
	11	Tanabe, Y. et al. (1998) "Specification of motor neuron identity by the MNR2 homeodomain protein," <i>Cell</i> 95: 67-80.					
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EXAMINEI SIGNATUR		DATE CONSIDERED					

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a checkmark here if English language Translation is attached.